

<b>Notice of Allowability</b>	Application No.	Applicant(s)	
	10/024,858	LEONARD ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 15 December 2005.
2. ☒ The allowed claim(s) is/are 25 and 26.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☒ Certified copies of the priority documents have been received in Application No. 08/817,911.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>11/22/05</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                               | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9. <input type="checkbox"/> Other _____.   |

**THURMAN K. PAGE**  
 SUPERVISORY PATENT EXAMINER  
 TECHNOLOGY CENTER 1600

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Response to Notice of Non-Compliant Notice under 37 C.F.R. 1.121 filed 12/15/05, the Request for Continued Examination (RCE) under 37 CFR §1.114 filed 11/22/05 and the Information Disclosure Statement (IDS) filed 11/22/05 is acknowledged.

Claims 25 and 26 are pending in this action. Claim 26 has been amended. Claims 25 and 26 are allowed.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/05 has been entered.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 11/22/05 was filed after the mailing date of the Notice of Allowance on 07/27/05. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

*Allowable Subject Matter*

Claims 25 and 26 are allowed.

The following is an examiner's statement of reasons for allowance:

The instant invention is drawn to a composition that reduces the incidence of nausea and vomiting associated with the administration of paroxetine, comprising paroxetine, or a pharmaceutically acceptable salt thereof, in a controlled and delayed release swallow pharmaceutical formulation that, upon administration, releases the paroxetine predominantly in the small intestine.

The primary reason for allowance is that the prior art (Johnson WO 92/09281) does not disclose nor fairly suggest a composition comprising paroxetine in both a controlled and delayed release formulation and does not teach a method of treating one or more diseases states as claimed in instant claim 26. Rather, the prior art merely indicates that delayed *or* controlled formulations were known, however, the prior art itself, does not teach or suggest a formulation comprising a controlled and delayed release formulation. Applicants specification contains and defines the terms 'controlled release' and 'delayed release' formulations. The instant specification also contains multiple examples demonstrating paroxetine compositions in controlled and delayed release formulations. The controlled and delayed release combination of paroxetine as instantly claimed provides an unexpected reduction in the side effects associated with the administration of paroxetine using, for example, swallow tablets. Hence beneficial and improved results are obtained through the use of a formulation of paroxetine having both controlled and delayed release, as instantly claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

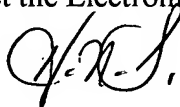
*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh



Patent Examiner

Art Unit 1615

January 09, 2006

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